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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,866	08/20/2003	Leigh T. Canham	124-1052	5193
23117	7590	10/05/2006	EXAMINER	
NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			ALSTRUM ACEVEDO, JAMES HENRY	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 10/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/643,866

Applicant(s)

CANHAM, LEIGH T.

Examiner

James H. Alstrum-Acevedo

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46-86 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 46-86 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 46-86 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 46-69, 71-73, 81, and 86, drawn to a method of implantation comprising implantation of a sample of resorbable or bioactive silicon into a living animal or human, classified in class 128, subclass 898.
- II. Claim 70 drawn to a method of accelerating or retarding the rate of deposition of a mineral deposit on silicon in a physiological electrolyte comprising the application of an electrical bias to the silicon, classified in class 128, subclass 898.
- III. Claims 74-76, drawn to a method of performing a bioassay comprising (a) supporting a cell line on a substrate; and (b) exposing the cell line to a pharmaceutical product; wherein the substrate comprises one or more of resorbable silicon, bioactive silicon, and biocompatible silicon, classified in class 702, subclass 19.
- IV. Claim 77, drawn to a method of forming a bond between living tissue and a material comprising (a) forming the material at least partly from bioactive silicon, and (b) bringing the bioactive silicon into contact with the living tissue, classified in class 128, subclass 898.
- V. Claim 78 and 86, drawn to a method of degrading a material and replacing it with living tissue comprising (a) forming a material at least partly from resorbable

silicon and (b) bringing the resorbable silicon into contact with living tissue, classified in class 128, subclass 898.

- VI. Claim 79, drawn to a method of enhancing mineral deposition on an implantable bioassay device having an integrated circuit comprising forming a layer of bioactive silicon on at least a portion of the bioassay device, classified in class 128, subclass 898.
- VII. Claim 80, drawn to a method of improving adhesion of bone to a surgical implant comprising forming a layer of bioactive silicon on at least a portion of the surgical implant, classified in class 128, subclass 898.
- VIII. Claims 82-83, drawn to a bioactive silicon, classified in class 424, subclass 724.
- IX. Claims 84-85, drawn to an electronic device for drug delivery comprising a bioactive silicon and a drug, classified in class 128, subclass 899.

The inventions are distinct, each from the other because of the following reasons:

Inventions VII and VI are directed to related methods resulting in the deposition of bioactive silicon onto a surface. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed the inventions as claimed are not obvious variants. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is

Inventions VIII and I-III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the

Art Unit: 1616

product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process of using that product, such as in a method of healing wounds by the application of wound healing glass powder comprising bioactive silicon.

Inventions IX and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process of using that product, such as in a method of delivering drug from a device comprising bioactive silicon that is located externally to the body of the subject receiving treatment.

Inventions II-VII and I are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as capable of use together and have different modes of operation (i.e. different method steps).

Inventions IX and II-VI are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the product cannot be used in the methods of groups II-VI.

Art Unit: 1616

Inventions IX and VIII are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because patentability of an electronic drug delivery device does not require the particulars of the subcombination. The subcombination has separate utility such as a component of a wound healing glass powder.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, require a different field of search (see MPEP § 808.02), and have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Election of Species

Claims (1) 46-59, 66, 72-81 and (2) 47, 54-55, 61-63, are generic to the following disclosed patentably distinct species: (1) kinds of silicon (i.e. resorbable, bioactive, and biocompatible) (claims 46-59, 66, 72-81) and (2) kinds of silicon porosity (i.e. meso-, micro-, and macroporous) (claims 47, 54-55, 61-63). Applicants are respectfully requested to make a species election **for initial examination purposes only**: (1) elect a one specific kind of silicon from the group consisting of (a) resorbable silicon, (b) bioactive silicon, and (c) biocompatible

Art Unit: 1616

silicon; and (2) elect a single silicon porosity selected from (i) mesoporous or (ii) microporous or (iii) macroporous.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

A telephone call requesting an oral election was not made due to the complexity of the instant restriction/species election. It is proper for the Examiner to send a written restriction/election requirement whenever said restriction/election is deemed complex (See MPEP § 812.01).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Art Unit: 1616

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

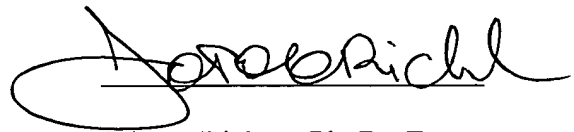
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James H. Alstrum-Acevedo, Ph.D.
Patent Examiner
Technology Center 1600

Application/Control Number: 10/643,866
Art Unit: 1616

Page 8

A handwritten signature in black ink, appearing to read "Johann Richter", written over a horizontal line. The signature is stylized with a large, looping initial "J" and a trailing flourish.

Johann Richter, Ph. D., Esq.
Supervisory Patent Examiner
Technology Center 1600